

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Application of: Jay S. Fine	:	Examiner: San Ming R. Hui
	:	
For Patent: <b>Methods and Therapeutic</b>	:	Group Art Unit: 1617
<b>Combinations for the</b>	:	
<b>Treatment of Demyelination</b>	:	Confirmation No. 6101
Serial No.: 10/701,244	:	
	:	Date: January 23, 2009
Filed: 11/04/2003	:	

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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Schering-Plough Corporation Kenilworth, New Jersey 07033-0530
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**Request for Reconsideration of Patent Term Adjustment**

**Under 37 C.F.R. §1.705(b)**

Sir:

In response to the Notice of Allowance and Notice of Patent Term Adjustment under 35 USC 154(b) ("Notice"), mailed on November 10, 2008, Applicants respectfully request reconsideration of the Patent Term Adjustment of 828 days noted on the Notice, and request that it be corrected to **1262 days**.

Applicants enclose herewith the fee set forth in 37 C.F.R. §1.18(e).

Applicants respectfully submit that a Patent Term Adjustment of 1262 days should be accorded to this application. In support thereof, Applicants have attached a

copy of the "AIPA Term Calculation Report " which summarizes the prosecution history of the present application, the grounds for adjustment under 37 C.F.R. § 1.702 applied to the prosecution history, and corresponding period of adjustment due under 37 C.F.R. §1.703. Also attached is a copy of the Patent Term Adjustments for this application from the PTO website.

As can be seen Applicants' calculation of the Patent Term Adjustment (PTA) is different from the PTA calculated by the PTO. It is believed that this discrepancy is based upon the District Court's ruling in *Wyeth v. Dudas* (No. 07-1492 D.D.C. September 30, 2008).

In view of the AIPA Term Calculation Report, it is believed that the PTA should be 1262 days and Applicants respectfully request the PTO to review the PTA.

Applicants reserve the right, under 37 C.F.R. §1.705(d), to request further revisions to the patent term adjustment, should the Office fail to note the revised patent term adjustment on the face of any patent issuing from the present application, or fail to timely issue any patent issuing from the present application.

Respectfully submitted,



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10/701,244	METHODS AND THERAPEUTIC COMBINATIONS FOR THE TREATMENT OF DEMYELINATION	01-22-2009::11:25:30
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### Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/701,244

Filing or 371(c) Date:	11-04-2003	USPTO Delay (PTO) Delay (days):	828
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	0
Post-Issue Petitions (days):	+0	Total PTA (days):	828
USPTO Adjustment(days):	+0	Explanation Of Calculations	

### Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
11-10-2008	Mail Notice of Allowance		
10-29-2008	Document Verification		
10-29-2008	Notice of Allowance Data Verification Completed		
10-07-2008	Date Forwarded to Examiner		
09-26-2008	Request for Continued Examination (RCE)		
10-07-2008	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		
10-01-2008	Mail-Record Petition Decision of Granted to Withdraw from Issue		
09-30-2008	Record Petition Decision of Granted to Withdraw from Issue		
09-26-2008	Petition Entered		
09-26-2008	Workflow - Request for RCE - Begin		
09-23-2008	Application Is Considered Ready for Issue		
09-18-2008	TC Return to Pubs		
09-09-2008	Mail PUB Notice of non-compliant IDS		
09-09-2008	PUB Notice of non-compliant IDS		
08-07-2008	Information Disclosure Statement considered		
08-07-2008	Information Disclosure Statement (IDS) Filed		
08-07-2008	Information Disclosure Statement (IDS) Filed		
01-09-2008	Pubs Case Remand to TC		
02-15-2008	Issue Fee Payment Verified		
02-15-2008	Issue Fee Payment Received		
01-09-2008	Pubs Case Remand to TC		
11-16-2007	Mail Notice of Allowance		
11-16-2007	Mail Examiner's Amendment		
11-14-2007	Notice of Allowance Data Verification Completed		
11-14-2007	Case Docketed to Examiner in GAU		
11-14-2007	Document Verification		
11-14-2007	Examiner's Amendment Communication		
10-18-2007	Information Disclosure Statement considered		
11-06-2007	Date Forwarded to Examiner		

10-26-2007	Response after Non-Final Action	
10-18-2007	Electronic Information Disclosure Statement	
10-18-2007	Information Disclosure Statement (IDS) Filed	
07-27-2007	Mail Non-Final Rejection	
07-23-2007	Non-Final Rejection	
06-02-2004	Information Disclosure Statement considered	
06-02-2004	Information Disclosure Statement considered	
01-21-2005	Information Disclosure Statement considered	
10-01-2004	Information Disclosure Statement considered	
10-01-2004	Information Disclosure Statement considered	
06-02-2004	Information Disclosure Statement considered	
06-02-2004	Information Disclosure Statement considered	
06-02-2004	Information Disclosure Statement considered	
06-02-2004	Information Disclosure Statement considered	
05-07-2004	Information Disclosure Statement considered	
04-22-2004	Information Disclosure Statement considered	
05-22-2007	Date Forwarded to Examiner	
05-11-2007	Response to Election / Restriction Filed	
04-12-2007	Mail Restriction Requirement	828
04-02-2007	Requirement for Restriction / Election	↑
03-21-2005	Preliminary Amendment	↑
01-21-2005	Information Disclosure Statement (IDS) Filed	↑
01-21-2005	Information Disclosure Statement (IDS) Filed	↑
10-01-2004	Information Disclosure Statement (IDS) Filed	↑
10-01-2004	Information Disclosure Statement (IDS) Filed	↑
10-01-2004	Information Disclosure Statement (IDS) Filed	↑
10-01-2004	Information Disclosure Statement (IDS) Filed	↑
04-22-2004	Information Disclosure Statement (IDS) Filed	↑
04-22-2004	Information Disclosure Statement (IDS) Filed	↑
06-02-2004	Electronic Information Disclosure Statement	↑
06-02-2004	Information Disclosure Statement (IDS) Filed	↑
06-02-2004	Electronic Information Disclosure Statement	↑
06-02-2004	Information Disclosure Statement (IDS) Filed	↑
06-02-2004	Electronic Information Disclosure Statement	↑
06-02-2004	Information Disclosure Statement (IDS) Filed	↑
06-02-2004	Electronic Information Disclosure Statement	↑
06-02-2004	Information Disclosure Statement (IDS) Filed	↑
06-02-2004	Electronic Information Disclosure Statement	↑
06-02-2004	Information Disclosure Statement (IDS) Filed	↑
06-02-2004	Electronic Information Disclosure Statement	↑
06-02-2004	Information Disclosure Statement (IDS) Filed	↑

05-07-2004	Information Disclosure Statement (IDS) Filed	↑
05-07-2004	Information Disclosure Statement (IDS) Filed	↑
03-25-2004	IFW TSS Processing by Tech Center Complete	↑
03-25-2004	Case Docketed to Examiner in GAU	↑
02-05-2004	Application Return from OIPE	↑
02-05-2004	Application Return TO OIPE	↑
02-05-2004	Application Dispatched from OIPE	↑
02-06-2004	Application Is Now Complete	↑
01-27-2004	Cleared by OIPE CSR	↑
12-16-2003	IFW Scan & PACR Auto Security Review	↑
11-04-2003	Initial Exam Team nn	↑

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## AIPA Term Calculation Report

APPLICATION INFORMATION			
Docket Number:	CV01679	User Name:	MacMillan, Keith
Application Number:	10/701,244	Firm/Company Name:	Schering-Plough Corporation
Filing Date:	11/04/2003	User Comments:	
Title/Inventor(s):	METHODS AND THERAPEUTIC COMBINATIONS FOR THE TREATMENT OF DEMYELINATION; Jay S. Fine, Bloomfield, NJ		01/22/2009 10:21:04 AM ET

AIPA TERM CALCULATION SUMMARY	
Calculation Mode:	Preliminary (1)
Earliest Referenced Application under 35 USC § 120, 121, or 365(c):	11 / 06 / 2002
Filing Date (US National Application):	11 / 04 / 2003
Net Adjustment Credits:	1360 Days
Net Adjustment Debits:	98 Days
Patent Term Adjustment:	1262 Days
AIPA Patent Term End Date:	04 / 21 / 2026 (2)
<p>(1) Based on your current data for this application, a complete calculation could not be performed. Certain required rules(s) are missing from this application. For a list of event and rule issues, see the Term Analysis tab.</p> <p>(2) Assumes payment of all maintenance fees, no intervening acts, and no 35 USC 156 regulatory extensions. Terminal disclaimer(s) filed in this case, if any, may result in an earlier term end date. Without adjustment, the term would end on 11/06/2022.</p>	

COMPARISON TO USPTO PAIR PTA TAB (3) (Based on PAIR Data from 01/22/2009)			
	PAIR PTA Tab	Your Calculation (1)	Comparison
Credit Days (USPTO Delay):	828	1360	x
Debit Days (Applicant Delay):	0	98	x
Total Patent Term Adjustment Days:	828	1262	x
(3) Comparison is shown for USPTO Delay, Applicant Delay, and Total Patent Term Adjustment fields displayed on USPTO PAIR Patent Term Adjustments (PTA) tab on 01/22/2009. See the full PAIR PTA tab, file wrapper (e.g., Notice of Allowance, PTA-related petitions), and issued patent for complete information on USPTO-calculated PTA.			

RULE CALCULATION SUMMARY (1) (4)						
Event	Rule Invoked	Related Event	Exclusion Days (5)	Debit Days (6)	Credit Days (7)	
A 11/04/2003 Filing Date under 35 USC 111(a) (US National Application)	<b>14-Month PTO First Action</b>  PTO must mail a notification under 35 USC 132 or a notice of allowance under 35 USC 151 not later than 14 months after the date on which the application was filed under 35 USC 111(a) or fulfilled the requirements of 35 USC 371 in an international application. Period of adjustment (credits) begins on the day after the date that is 14 months after the date on which the application was filed under 35 USC 111(a) or fulfilled the requirements of 35 USC 371 and ending on the date of mailing of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(i); 37 CFR 1.702(a)(1), 1.703(a)(1).	<i>First PTO Action:</i> 04/12/2007 Restriction / Election-of-Species			828	
B 11/04/2003 Filing Date under 35 USC 111(a) (US National Application)	<b>3-Year PTO Issue of Patent</b>  PTO must issue a patent within 3 years (not including exclusions) after the date on which the application was filed under 35 USC 111(a) or the national stage commenced under 35 USC 371(b) or (f) in an international application. Period of adjustment (credits) begins on the day after the date that is 3 years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 USC 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the sum of the listed exclusionary periods. 35 USC 154(b)(1)(B); 37 CFR 1.702(b), 1.703(b).  You have elected to analyze this rule without applying the USPTO 37 CFR § 1.703(f) Actual Delay limitation in determining Credit Days under this rule. This is consistent with DC District Court ruling in Wyeth et al. v. Dudas, No. 07-1492 (D.D.C. September 30, 2008).	<i>Issue Date:</i> 05/19/2009 Issue Date			691	

C	<p>04/12/2007 Restriction / Election-of-Species</p>	<p><b>3-Month Applicant Response to Notice or Action</b></p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p>	<p>Applicant Response: 05/11/2007 Response to Election-of-Species/ Restriction Filed</p>	0	
D	<p>05/11/2007 Response to Election-of-Species / Restriction Filed</p>	<p><b>4-Month PTO Response to Applicant Reply</b></p> <p>PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 or in compliance with 37 CFR 1.113(c) was filed and ending on the mailing date of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(ii); 37 CFR 1.702(a)(2), 1.703(a)(2),(3).</p>	<p>PTO Response: 07/27/2007 Non-final Action</p>	0	
E	<p>07/27/2007 Non-final Action</p>	<p><b>3-Month Applicant Response to Notice or Action</b></p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p>	<p>Applicant Response: 10/26/2007 Reply after Non-final Action under 37 CFR 1.111</p>	0	
F	<p>10/26/2007 Reply after Non-final Action under 37 CFR 1.111</p>	<p><b>4-Month PTO Response to Applicant Reply</b></p> <p>PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 or in compliance with 37 CFR 1.113(c) was filed and ending on the mailing date of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(ii); 37 CFR 1.702(a)(2), 1.703(a)(2),(3).</p>	<p>PTO Response: 11/16/2007 Notice of Allowance under 35 USC 151</p>	0	



<p>G</p> <p>11/16/2007 Notice of Allowance under 35 USC 151</p>	<p><b>3-Month Applicant Response to Notice or Action</b></p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p>	<p><i>Applicant Response:</i></p> <p>02/15/2008 Issue Fee Payment under 35 USC 151</p>	<p>0</p>	
<p>H</p> <p>09/26/2008 Request for Continued Examination under 35 U.S.C. 132(b)</p>	<p><b>Exclusion for Continued Examination</b></p> <p>3-Year PTO Issue Requirement does not include the period consumed by continued examination of the application under 35 USC 132(b), beginning on the date on which a request for continued examination of the application under 35 USC 132(b) was filed and ending on the date the patent was issued. 35 USC 154(b)(1)(B)(i); 37 CFR 1.702(b)(1), 1.703(b)(1).</p>	<p><i>Issue Date:</i></p> <p>05/19/2009 Issue Date</p>	<p>236</p>	
<p>I</p> <p>11/10/2008 Notice of Allowance under 35 USC 151</p>	<p><b>3-Month Applicant Response to Notice or Action</b></p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p>	<p><i>Applicant Response:</i></p> <p>05/19/2009 Issue Date</p>	<p>98</p>	
<p>Total Exclusion, Debit, and Credit Days:</p>			<p>236</p>	<p>1519</p>
<p>Overlap Days (8) :</p>			<p>0</p>	<p>159</p>
<p>Net Exclusion, Debit, and Credit Days:</p>			<p>236</p>	<p>1360</p>
<p>Patent Term Adjustment Days (9) :</p>			<p>98</p>	<p>1262</p>

- (4) Calculations of Debit, Credit, and Exclusion Days are determined by the rule assignments, assignments of related events, and analysis options in the Apply Term Rules tab. The patent professional using this system is responsible for reviewing and updating the Apply Term Rules tab to ensure all data is complete, correct, and consistent with their judgment and interpretation of applicable legal authority.
- (5) Exclusion Days are periods which are not included in determining the end of the 3-year period after the date on which the application was filed under 35 USC 111(a), or the national stage commenced under 35 USC 371(b) or (f) in an international application, used to determine credits under the 3-Year PTO Issue of Patent rule. See 35 USC 154(b)(1)(B)(i)-(iii); 37 CFR 1.702(b)(1)-(5); 1.703(b)(1)-(4).
- (6) Debit Days are days where grounds for reduction of period of adjustment of patent term exist. See, e.g., 37 CFR 1.704. Debit Days are sometimes referred to as Applicant Delay.
- (7) Credit Days are days where grounds for adjustment of patent term exist. See, e.g., 37 CFR 1.702, 1.703. Credit Days are sometimes referred to as USPTO Delay.
- (8) To the extent credit periods overlap other credit periods, debit periods overlap other debit periods, or exclusion periods overlap other exclusion periods, overlaps are subtracted so that each calendar day generates at most one credit day, one debit day, and one exclusion day.
- (9) Patent Term Adjustment Days equals Net Credit Days minus Net Debit Days, but is not less than zero.